JUN 2 5 2001

Fisher & Paykel HEALTHCARE

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11 December, 2000

K003894

510(k) Summary of Safety and Effectiveness Information

Trade Name:	**Fisher & Paykel Healthcare Oracle Oral Mask**
Classification Name:	Accessory to Noncontinuous ventilator (IPPB) - 73 BZD Anesthesiology Devices, 21 CFR §868.5905 (Class II)
Predicate Device:	OPAP Inc, OPAP®, K991926

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92:

(a)(1) - (a)(3) Refer to information above and concluding this summary.

(a)(4) Description of the Device

The Oral Mask is an accessory to a Noncontinuous ventilator (IPPB) according to 21 CFR §868.5905. It constitutes the patient to ventilator interface in a noncontinuous ventilator system.

The Oral Mask consists of a mouthpiece and flexible breathing tube. The flexible breathing tube is connected to the output breathing tube of the ventilator. The ventilator supplies air at CPAP or Bilevel pressures (typically in the range 3 - 20 cm H_2O) which is available at the Oral Mask mouthpiece.

The mouthpiece is positioned in the patient's mouth during CPAP or Bilevel treatment. Features of the mouthpiece ensure the desired positive airway pressure is delivered to the patient with minimal leakage and that the mouthpiece is retained in the mouth while asleep.

The flexible breathing tube provides a transition between the more rigid output tube of the ventilator and the mouthpiece, facilitating freedom of movement while maintaining circuit integrity. An exhaust port adjacent to the mouthpiece provides a means to purge exhaled gases from the breathing circuit.

510(k) Summary of Safety and Effectiveness Information (continued)

(a)(5) Statement of the Intended Use

The Oral Mask is intended for single patient adult use by individuals who have been diagnosed by a physician as requiring CPAP or Bilevel ventilator treatment. A CPAP or Bilevel ventilator is typically used to treat obstructive sleep apnea (OSA) and may be used in the home, hospital or laboratory. The positive air pressure supplied by the ventilator is delivered via the Oral Mask to the patient's mouth.

The Oral Mask is designed to function as intended for up to 12 months of daily use when cared for as specified by the User Instructions.

(a)(6) Technological Characteristics Summary

The technological characteristics of the Oral Mask are equivalent to the predicate device listed above.

The Oral Mask mouthpiece is designed to assure unobstructed access to the patient's airway and to create an air-seal around the patient's mouth to facilitate sustained delivery of positive airway pressure. The Oral Mask mouthpiece is retained inside the mouth during sleep by action of the SnapFlap™ which rests against the patient's cheeks. The SnapFlap™'s flexibility allows the mouthpiece to accommodate a wide range of face shapes and sizes.

The mouthpiece is connected to the elbow of a flexible breathing tube. The elbow incorporates a pattern of holes which constitute the exhaust port for bias airflow. The exhaust port allows the purging of exhaled gases. Product labeling states that the Oral Mask must not be used unless connected to a ventilator supplying the minimum specified ventilation pressure at which sufficient bias airflow is available to guarantee minimal re-breathing.

The flexible breathing tube allows the patient freedom of movement by way of the elbow and swivel joint rotation and flexure of the tubing itself. The swivel joint at the end of the flexible breathing tube is a press fit to industry standard breathing tube (ISO 5356-1, ASTM F1054: 22mm conical fitting). This allows effective connection to a wide range of CPAP and Bilevel ventilators.

The swivel joint incorporates two ports which may be optionally used to gain access to the breathing tube gas flow. For example, oxygen may be added through one port while the other port accommodates a pressure transducer. Typically, this type of operation is performed by a sleep laboratory during patient diagnosis and titration. When not in use, the swivel joint ports may be blocked off by the swivel port cap.

The Oral Mask is manufactured from materials that meet appropriate USP and FDA requirements.

510(k) Summary of Safety and Effectiveness Information (continued)

(b)(1) and b(2) Discussion of Non-Clinical and Clinical Tests

Tests performed on the Oral Mask demonstrate substantial equivalence to the predicate device.

Non-clinical tests have demonstrated effective performance in terms of strength, durability, pressure and flow characteristics, and conformance of connections to industry standards. Clinical trials have demonstrated successful treatment of OSA by the use of the Oral Mask.

(b)(3) Conclusions Demonstrating Safety, Effectiveness and Performance

When used as intended, the Oral Mask has been shown to be as safe and effective as the predicate device. Specifically:

- The Oral Mask is a safe patient to ventilator interface when used as an accessory to a Noncontinuous ventilator
- The Oral Mask is an effective means of delivering positive airway pressure in the treatment of OSA
- The Oral Mask is a reliable device when used and maintained as specified in the Device Instructions

This information verifies that the Oral Mask is equivalent to the predicate device in terms of safety, effectiveness and performance.

signed: D.K. Alexander date: 12/12/2000

Darryn Alexander
Fisher & Paykel Healthcare Ltd

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Darryn Alexander
Fisher & Paykel Healthcare Ltd.
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Re: K003894
Oral Mask
Regulation Number: 868.5905
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: June 8, 2001
Received: June 14, 2001

Dear Mr. Alexander:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

[510(k)] Number: K003894

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11 December, 2000

Fisher & Paykel Healthcare - Oral Mask

PREMARKET NOTIFICATION 510(k)
INDICATIONS FOR USE STATEMENT

The Fisher & Paykel Healthcare Oral Mask is an accessory to a Noncontinuous ventilator (IPPB) as per 73 BZD, 21 CFR §868.5905.

The Oral Mask is indicated for use by adults requiring CPAP or Bilevel ventilator treatment in home, hospital and laboratory environments for the treatment of Obstructive Sleep Apnea (OSA). It constitutes the patient to ventilator interface in a noncontinuous ventilator system. The device administers positive airway pressure orally. The Oral Mask is for single patient use on the prescription of a suitably qualified physician.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003894

Prescription Use
(Per 21 CFR §801.109)